EXHIBIT B

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Legal Lyme

Another "Chronic Lyme" VIP disciplined by NY medical authorities: Bernard Raxlen

Another "Lyme literate" NY physician is on probation and under orders to clean up his act. Will other physicians treating "chronic Lyme" take note?

Jann Bellamy on November 9, 2017

Bernard Raxlen, MD, who devotes more than 90% of his practice to the treatment of so-called "chronic Lyme" disease, is on a three-year probation imposed by the New York State Board for Professional Medical Conduct (BPMC). Raxlen agreed to probation and a lengthy list of practice requirements last month following allegations, filed in September, of negligence, incompetence, gross negligence, gross incompetence, and failure to maintain adequate patient records. In doing so, he becomes the second "Lyme literate" VIP disciplined by the NY medical authorities this year. Based on similar charges of professional misconduct, David Cameron, MD, was also put on probation with numerous practice restrictions in June.

Who is Bernard Raxlen, MD?

Raxlen is a psychiatrist and solo "chronic Lyme" practitioner in New York City who says he's "successfully treated" over 3,500 cases of tick-borne disease in

the past 15 years. (He named his practice "Lyme Resource Medical of New York.") He touts a "total comprehensive treatment program which utilizes both oral and intravenous (IV) antibiotic treatment." It doesn't come cheap, either. An initial visit with Raxlen costs $1,200 with follow-up visits between $600 and $700. A PICC-line insertion (presumably for long-term antibiotics) is $750 and a "nutritional IV" is $150. He does not accept public or private insurance.

Raxlen has a history of disciplinary actions against him in two states stretching back almost 20 years. In Connecticut, where he was formerly licensed, he was reprimanded and paid a total of $35,000 in civil penalties in two cases arising out of his refusal to provide patient records to the Health Department and insurance companies, even though patients had signed releases. He was also disciplined for inappropriate prescribing and failing to maintain malpractice insurance. Because these infractions constituted professional misconduct in New York as well, he was subject to two disciplinary actions in that state, resulting in censure, reprimand and a $2,500 fine.

According to the *Chicago Tribune*, Raxlen had other professional misconduct charges brought against him by Connecticut authorities but they were ultimately dropped. The *Tribune* reported that, in one case, Raxlen was charged with telling a patient with Lou Gehrig's disease (ALS) that she had Lyme disease and treating her with an illegal drug from Germany. He told the reporter that the relationship between ALS and Lyme was "unclear," even though ALS experts concluded that there was no evidence of a connection.

Per his New York State Department of Health physician profile (just type his name into the search engine), Raxlen completed residency training in psychiatry and lists his specialty as psychiatry, but he is not board certified in any specialty. He did not train in internal medicine, family medicine or pediatrics (although he treats pediatric patients), specialties that normally treat routine Lyme infections. Nor did he train in infectious diseases, experts to whom patients with more complicated cases of Lyme would normally be referred by other practitioners.

Yet, he is described by the International Lyme and Associated Disease Society (ILADS) as a "leader in Lyme disease treatment and research." In fact, he is a founding member of ILADS, former Secretary of the Board, and has taught a number of ILADS courses. He was a co-author of the original ILADS guidelines for the treatment of tick-borne diseases. Despite their troubling disciplinary status, both he and David Cameron are scheduled to speak at the ILADS Annual Scientific Conference, which starts today in Boston.

How can this be? How can one be a leading light in ILADS with a disciplinary history like Raxlen's and no graduate medical education in infectious diseases?

"Lyme literate" physicians like Raxlen have fabricated a disease they call "chronic Lyme," which they regularly "diagnose" and treat with long-term antibiotics, sometimes for months to years. Board-certified infectious diseases doctors and other "conventional" physicians all agree that "chronic Lyme" is *not* a valid diagnosis and rely on well-conducted trials showing that long-term antibiotics do not substantially improve the outcome for patients diagnosed with so-called "chronic Lyme." Long-term antibiotics can, in fact, result in serious harm, including death, a subject our good friend Orac covered recently over on Respectful Insolence. Orac's post nicely summarizes the differences between real Lyme disease and "chronic Lyme," "a prototypical fake medical diagnosis," and the dangers of long-term antibiotics, as have posts on SBM, here, here, here, and here.

The CDC, the Infectious Diseases Society of America (IDSA), the American Academy of Pediatrics, the American College of Physicians, the *Medical Letter* and the American Academy of Neurology all reject the notion that "chronic Lyme" exists and that long-term antibiotics are an appropriate treatment. There is something called "post-treatment Lyme disease syndrome," but responsible medical authorities do not equate this syndrome with the nebulous symptoms and unvalidated lab tests of "chronic Lyme" and specifically reject the utility long-term antibiotic treatment based on well-conducted clinical trials. None of this is

to say that patients who've been told they have "chronic Lyme" are not truly suffering, a fact that makes "Lyme literate" practices all the more reprehensible.

None of this stopped "Lyme literate" doctors from banding together to form ILADS and issuing their own guidelines for the diagnosis and treatment of "chronic Lyme," guidelines based on very low levels of evidence that are accepted only by themselves and, in contrast to the IDSA guidelines, no other professional medical organization. ILADS teaches physicians and other practitioners how to become "Lyme literate." ILADS, again in contrast to IDSA, is not an ACCME-accredited provider of continuing medical education although, for some inexplicable reason, the Westchester [County, NY] Medical Society has teamed up with ILADS and is using its accrediting authority to grant CME credit for some of the talks (also here) at the ILADS Scientific Conference.

Despite the lack of evidence that "chronic Lyme" is a valid diagnosis, and the lack of efficacy as well as the risks of long-term antibiotic treatment, ILADS healthcare providers currently treat more than 100,000 patients with "chronic Lyme" and tick-borne diseases in the USA and around the world. Given media reports that patients can spend $10,000 to $35,000 for treatment, "Lyme literacy" translates into millions of dollars for practitioners.

While it may be profitable, "Lyme literate" doctors risk running afoul of state medical boards. Raxlen is just one among ILADS-trained, "Lyme literate" physicians who have had their medical practices questioned by their peers, up to and including discipline imposed by state authorities (also, here and here).

With that background, let's look at the allegations against Raxlen and the terms of his probation.

The BPMC v. Raxlen

New York's medical misconduct procedures do not require the physician charged to stipulate to any particular acts of misconduct as a condition of settling his case. The physician can, as Raxlen did here, simply state he is unable to "successfully defend against at least one of the acts of misconduct alleged" and agree to the imposition of sanctions. This means the allegations in the state's Statement of Charges were never proven, as it was unnecessary to reach a decision on the factual issues once Raxlen agreed to a settlement. However, per the Office of Professional Medical Conduct's (OPMC) standard procedures, the allegations were based on expert review of Raxlen's patients' records and they remain uncontested by him.

The allegations of misconduct arise out of Raxlen's care of eight patients. As is typical of "chronic Lyme" diagnosis and treatment, patients (whose identities are protected) presented with a variety of disparate symptoms, such as:

- Patient A: freezing, burning, air hunger, weakness, fatigue, neck pain and intestinal pain.
- Patient E: fatigue, migraines, neck pain, joint pain, numbness and tingling, irritability, sound, light and temperature sensitivity and nonrestorative sleep.
- Patient G: back pain, abdominal pain, feet pain, extremity weakness, anxiety, depression and mood swings.
- Patient H (who got the Hickman catheter and numerous antibiotics mentioned below): mouth, teeth and jaw pain, confusion, forgetfulness, irritability and mood swings.

Diagnosis and treatment of "chronic Lyme" is never mentioned, a wise decision on the part of the BPMC prosecutors in light of the ill-conceived New York law protecting "Lyme literate" doctors from prosecution

> "based solely upon the recommendation or provision of a treatment modality by a licensee that is not universally accepted by the medical profession, including but not limited to, varying modalities used in the treatment of lyme disease and other tick-borne diseases.

Instead, the BPMC focused on the fact that Raxlen had failed in the most basic tenets of good medical care, although the fingerprints of "chronic Lyme" diagnosis and treatment, such as failure to consider alternative diagnoses, prescribing IV antibiotics and using a Hickman catheter, are all over the charges. The charges included:

- Repeatedly failing to perform or note in the patient's chart a comprehensive history and appropriate physical exam, including (despite his being a psychiatrist) a psychiatric history, neuropsychological testing and mental health status exam.
- Failing to construct a differential diagnosis and pursue a thorough diagnostic evaluation prior to instituting a treatment plan.
- Inappropriate prescribing, including prescribing Rifampin for a patient on Tamoxifen and prescribing addictive medications prior to a making a diagnosis and without considering non-addictive treatment.
- Inappropriately relying on Applied Kinesiology (which is quackery) to formulate a diagnosis.
- Placement of a Hickman catheter without medical necessity.

- Inappropriately administering antibiotics, including intravenous Invanz, Clindamycin, Flagyl, Rifampin, Minocycline, Mepron, Plaquenil and Bactrim, all of these for *one patient*.
- Failure to present or note in the patient's chart potential risks, benefits, side effects and safe use of prescribed medications.
- Failure to appropriately identify, address, and/or follow-up on potential side effects.
- Treating inappropriately with an ongoing and/or escalating medication regimen without appropriate physical exams and clinical reassessment for consideration of alternative diagnoses and treatment.
- Poor record-keeping.

These allegations resulted in charges of negligence, incompetence, gross negligence, gross incompetence, and failure to maintain adequate patient records. As noted, Raxlen agreed to a three-year probation in addition to the imposition of conditions on his practice. He must, among other things:

- Communicate to patients the nature of his medical role, whether it be a primary care physician responsible for the patient's general medical condition, or for a defined or limited purpose, and/or as a practitioner of a particular medical specialty.
- Obtain written informed consent addressing all aspects of treatment and document same, including documentation of all discussions with the patient about the nature and scope of his evaluation and treatment and the patient's need to pursue "conventional medical care elsewhere."
- Document all histories and physicals.
- Refer patients to primary care physicians, specialists or consultants for further evaluation and/or treatment where medically warranted and provide these physicians with all relevant patient information.

- Cooperate fully with the state in enforcing the Consent Order and timely respond to all state requests for written periodic verification of his compliance and all documents.

What now?

Based on a birthdate of 1938 in his state physician profile, Raxlen is either already, or soon will be, 79 years old. One wonders whether he will continue his practice in face of these new sanctions, although his website is still trying to attract patients.

Sadly, the "chronic Lyme" lobby responsible for passing the law protecting "Lyme literate" doctors has its sights set on even greater rewards. Several bills are pending in the NY legislature which would force insurers to cover "chronic Lyme" treatment (Assembly Bill 114, Senate Bill 4713, Senate Bill 670). Other bills give them the opportunity to argue in yet another venue for insurance coverage. (Assembly Bill 4863, Senate Bill 2168, Assembly Bill 6927).

In any event, it is commendable that the Board for Professional Medical Conduct has not let New York's unfortunate law get in the way of its prosecuting physicians who take advantage of patients with a diagnosis of "chronic Lyme," no matter how they frame the specific charges. With two leading NY "Lyme literate" physicians now on probation and under strict orders to clean up their acts, it remains to be seen what effect this might have on other "Lyme literate" doctors in the state.

Posted in: Legal, Lyme **Tagged in:** Bernard Raxlen, chronic Lyme disease, legal decision, Lyme-literate MDs, new york

Posted by Jann Bellamy

Jann J. Bellamy is a Florida attorney and lives in Tallahassee. She is one of the founders and Board members of the Society for Science-Based Medicine (SfSBM) dedicated to providing accurate information about CAM and advocating for state and federal laws that incorporate a science-based standard for all health care practitioners. She tracks state and federal bills that would allow pseudoscience in health care for the SfSBM website. Her posts are archived here.

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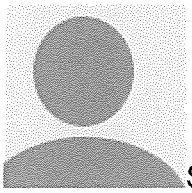
-  SchroedingersDog

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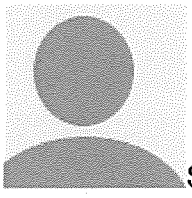
-  SchroedingersDog

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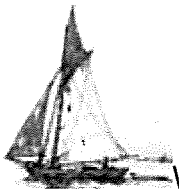
-  Windriven

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